Incident Report

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| **Organisation name:** |  |
| **Trial(s) affected:** |  |
| **Trial number(s) of affected patients *(if applicable)*** |  |
| **Name of IMP affected *(if applicable)*** |  |
| Details of the incident:*(Include date(s) incident occurred, how/when it was identified, why it occurred and, where applicable, trial numbers of patient(s) affected and IMP(s) affected)* |
| **Corrective action:***(Detail measures that were taken to address the incident and/or minimise its impact. Include date(s) of implementation/planned implementation and person(s) responsible)* |

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| **Preventative action:***(Detail measures that have been or that will be implemented to prevent future occurrences. Include date(s) of implementation/planned implementation and person(s) responsible)* |

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| **Form completed by:** |
| **Name:** |  | **Job title:** |  |
| **e-mail:** |  | **Tel no:** |  |
| **Signature:** |  | **Date:** |  |

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| **Date received:** |  |
| **Reviewed by:** |  |
| **For all incidents meeting criteria for referral or discussion per SOP T69:** |
| **Potential serious breach/urgent safety measure?** | **Yes**[ ] *If yes, add details in Comments box below***No**[ ]  |
| **Requires referral** **to Regulatory?** | **Yes**[ ] **No**[ ]  |
| **Requires referral** **to Stats?** | **Yes**[ ] **No**[ ]  |
| **Date discussed with STC /TGL** |  |
| **Comments:** |
|  |
| **PLEASE ENTER DETAILS ON TRIAL INCIDENT LOG FOR ALL TRIAL(S) AFFECTED & FILE REPORT IN APPROPRIATE TMF(S)** |